Entry of the proposed amendment and reconsideration of the above-identified application is respectfully requested in view of the following remarks:

REMARKS

In order to reduce the issues in the event of an appeal, claims 1-4 and 9-12, directed to an oral medicinal composition, have been cancelled. All of the claims present in this application are now directed to a method of administering a medicinal composition to a patient.

Independent claim 5 has been amended to more clearly define the "internal" administration of the medication to the patient. Thus, the claim has been amended to state that once the aqueous medicinal composition is foamed, the foam is deposited in the oral cavity of the patient without added water, and then the patient then swallows the foam or allows the foam to liquefy prior to swallowing. This is what was meant by "internal use" as added by the last amendment. The Examiner interpreted "internal use" broadly as for use in the oral cavity. Support for the limitations added to claim 5 are believed to be set forth at page 4, last paragraph, where an object of the invention is to dose a patient with medicine "with no need of water." Further support is believed to be set forth at page 5, second full paragraph, wherein it is stated that the liquid dosage form is prepared into a foam for administration to allow the resulting foam to again resume the liquid form after administration such that the oral liquid dosage form can be dosed with no water and readily swallowed with no rapid pouring into the throat. Again, at the bottom of page 6, it is stated that by foaming the oral medicinal composition prior to administration and then gradually allowing the foam composition to resume the initial liquid form, the oral medicinal composition can be readily administered with no irritation during administration without any water supply. At page 9, first full paragraph, it is

stated that the oral medicinal composition can be applied to the throat in a foamy state. Finally, at page 20, last line of the application, it is stated that the composition of the invention is preferable for administration to patients with swallowing difficulty. This latter passage provides explicit support for claim 17. New claims 14-16 are clearly supported by original claims 10-12.

Claims 5-7 have been rejected under 35 USC 102(a) as being anticipated by Saferstein et al. (U.S. 6,086,856). The Examiner states that the prior reference is drawn to an oral formulation comprising a medicament and a foaming agent, and that the patent discloses a system for delivering a foaming oral composition. The rejection is respectfully traversed.

In the last Office Action, applicants argued that the claimed invention distinguished over the applied reference inasmuch as the applied reference did not disclose a medicinal composition for internal use. Claim 5, which is the sole independent claim remaining in this application, is directed to a method of administering an oral composition in which the patient must swallow the composition. The method of the invention involves foaming the medication so as to allow the medication to be easily swallowed as the foam slowly liquefies from the oral cavity or the foam itself is swallowed and is not as harsh on the throat as would a slug of liquid from normal liquid dose applications.

The applied reference is simply directed to an oral hygiene system and a method of applying a medicine to the oral cavity. Saferstein et al. does not anticipate the claimed method inasmuch as the composition is not intended to be swallowed, and there does not appear to be any discussion in the patent for swallowing the composition or any advantages of first foaming the composition that is then intended to be swallowed by the

patient. All of the disclosure is directed to oral hygiene formulations such as mouthwashes, rinses, and dentifrices as set forth at column 1, lines 23-35. All of the examples in the patent are directed to mouth rinses such as for mouthwash, anti-plaque, etc. Accordingly, inasmuch as Saferstein et al. is not concerned with administering a foamed medicinal composition to the patient whereby the patient has to swallow the medication, i.e., the internal use, this patent does not anticipate any of claims 5-7. Withdrawal of the rejection is respectfully requested.

Claim 8 has been rejected under 35 USC 103 as being unpatentable over the disclosures of Saferstein et al. The Examiner states that Saferstein et al. discloses an oral foaming composition comprising polyethylene glycol, polysorbate, and sodium lauryl sulfate. The Examiner states that the reference does not disclose the exact mixture as set forth in claim 8. The Examiner takes the position that the combination recited in claim 8 would be well within the level of skill in the art. The rejection is respectfully traversed.

For the reasons as specified above, it is believed that Saferstein et al. does not suggest the method which is now recited in independent claim 5 and which method is incorporated into the dependent claims such as claim 8. Again, Saferstein et al. is concerned with a medicinal composition that is applied to the oral cavity and not swallowed. Inasmuch as claim 5 clearly recites the positive recitation that the patient must swallow the composition, it is believed that Saferstein et al. does not anticipate or suggest the claimed method. The claimed invention is directed to administering a medicine internally to a patient wherein it is difficult or painful for the patient to swallow the composition. Thus, it has been found that by foaming an aqueous composition, the foam can be inserted into the oral cavity of the patient and either swallowed and, due to the light density of the foam, not cause pain as would a slug of liquid, or the foam

composition can be slowly reliquified in the oral cavity and swallowed by the patient, again without a slug of liquid needed to be swallowed. The applied Saferstein et al. reference does not suggest the advantages of the claimed method. The patent is simply directed to an oral cavity composition such as mouthwashes and mouthrinses, and which is not intended to be swallowed.

In view of the amendment to claim 5, the sole independent claim in this application, it is believed that all of the claims remaining in this application and solely directed to a method of applying a medicinal composition to a patient distinguish over the prior art, and applicants respectfully solicit favorable action on claims 5-8 and 13-17.

Respectfully submitted,

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